IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MISSISSIPPI
OXFORD DIVISION

AMERICAN HEALTH CARE ASSOCIATION, *et al*., Plaintiffs, v. SYLVIA MATHEWS BURWELL, Secretary of Health and Human Services, *et al*., Defendants.	CIVIL ACTION NO. 3:16-cv-00233-MPM-RP

DEFENDANTS' RESPONSIVE MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

INTRODUCTION

Acting on her expressly delegated authority to protect the health and welfare of nursing home residents under Medicare and Medicaid, the Secretary of Health and Human Services has enacted a regulation that prohibits nursing homes that participate in these programs from entering into a pre-dispute agreement for binding arbitration with a resident or resident's representative. 42 C.F.R. § 483.70(n)(1). The regulation is based on a review of nearly 1,000 comments submitted in response to a notice of proposed rulemaking and other materials on this issue, including letters from members of Congress. After reviewing the wide range of views expressed in those comments and materials, the Secretary – through the Centers for Medicare & Medicaid Services ("CMS") – determined that a prohibition on pre-dispute arbitration agreements is in the best interests of nursing home residents.

The plaintiffs now seek a preliminary injunction against implementation of the regulation, which is set to become effective on November 28, 2016. The plaintiffs cannot, however, meet the requirements for preliminary relief. First, the plaintiffs are unlikely to

succeed on the merits: The regulation falls well within the Secretary's statutory authorities, including her authority to impose "other requirements" on nursing homes that voluntarily participate in Medicare or Medicaid, and to establish "other rights" to protect and promote the health, welfare, and rights of residents of such facilities, 42 U.S.C. §§ 1395i-3(c)(1)(A)(xi), (d)(4)(B), 1396r(c)(1)(A)(xi), (d)(4)(B); the regulation does not conflict with the Federal Arbitration Act, 9 U.S.C. § 2, which only requires courts to enforce arbitration agreements according to their terms; the volume and range of the materials considered by CMS, and the thoroughness of its consideration, belie plaintiffs' assertion that the decision was "arbitrary and capricious" under the Administrative Procedure Act; and the Secretary has complied with the purely procedural requirements of the Regulatory Flexibility Act, 5 U.S.C. §§ 601-612. This alone dooms the plaintiffs' motion.

Second, the other requirements for preliminary relief also militate against the motion. Plaintiffs' assertions of irreparable harm are rife with speculation, including claims that implementation of the regulation will prompt a "spike" in "meritless lawsuits" by members of the "plaintiffs' bar" seeking "windfall settlements," and that nursing homes might refuse to comply with the regulation, prompting CMS to impose the maximum statutory penalty and bankrupting the facilities. On the other side of the balance, many nursing home residents are frail, elderly, and/or disabled, and they are asked to sign binding arbitration agreements at an "extremely stressful" time, binding them to one means of resolving any future dispute with the facility, some of them for the rest of their lives. (Tellingly, consumer groups do not seem to be clamoring for the "right" to enter into pre-dispute arbitration agreements with nursing homes.) These and other injuries to the residents outweigh any imaginable harm to the nursing homes from not using such agreements, and the public interest strongly favors allowing the challenged regulation to go into effect.

Therefore, plaintiffs' motion for preliminary injunction must be denied.

STATUTORY AND REGULATORY BACKGROUND

I. Medicare, Medicaid, and Defendants' Role

Under the Social Security Act, the Medicare and Medicaid programs provide health insurance coverage for persons who are elderly, have a severe disability, or have very low income. *See* 42 U.S.C. §§ 1395-1396w-5. Medicare provides coverage for people who are age 65 or older, and for people who either suffer End-Stage Renal Disease or have received Social Security Disability Insurance for a certain length of time. *See id*. §§ 1395-1395*lll*. Medicaid provides coverage for low-income individuals whose medical insurance is inadequate. *See id*. §§ 1396-1396w-5. Medicare is operated by the federal government, and Medicaid is a joint federal-state program.

Under both Medicare and Medicaid, health care services are provided by private organizations and health care professionals who meet the statutory and regulatory requirements for participation. Participation in either Medicare or Medicaid is voluntary. *See, e.g.*, *Burditt v. Dep't of Health & Human Servs*., 934 F.2d 1362, 1376 (5th Cir. 1991). If a provider chooses to participate, it enters into an agreement under which it agrees to be bound by the program's conditions of participation. *See* 42 U.S.C. § 1395cc.

Medicare and Medicaid are administered by the Secretary of Health and Human Services, acting through the Centers for Medicare & Medicaid Services. *See, e.g.*, *id*. §§ 1395i-3, 1395kk, 1395hh, 1396a, 1396r. Congress has entrusted the Secretary with "exceptionally broad authority" in administering both programs. *See Wisconsin Dep't of Health & Family Servs. v. Blumer*, 534 U.S. 473, 497 (2002) (quoting *Schweiker v. Gray Panthers*, 453 U.S. 34, 43 (1981)); *see also Sebelius v. Auburn Reg'l Med. Ctr*., 133 S. Ct. 817, 826 (2013) ("Congress vested in the Secretary large rulemaking authority to administer the Medicare program.");

Arkansas Dep't of Health & Human Servs. v. Ahlborn, 547 U.S. 268, 275 (2006) (noting that administration of Medicaid "is entrusted to the Secretary of Health and Human Services . . . who in turn exercises his authority through the Centers for Medicare and Medicaid Services").

II. Long-Term Care Facilities

Long-Term Care ("LTC") facilities, often called nursing homes, provide residential nursing services, medication, rehabilitation, and other services for elderly and disabled persons. In light of the circumstances of the residents, "admission to a LTC facility is usually an extremely stressful time for the resident and his or her family. The resident may have a serious injury, surgery, or illness, [may be] removed from their usual living arrangements, [or may be] admitted to a facility for an indeterminate period of time." 81 Fed. Reg. 68,688, 68,796 (Oct. 4, 2016). Many residents end up spending "an extended period of time" in an LTC facility. *Id*. at 68,794. LTC facilities that participate in Medicare are officially known as "skilled nursing facilities," and those that participate in Medicaid are officially known as "nursing facilities."

In the Nursing Home Reform Act, part of the Omnibus Budget Reconciliation Act of 1987 ("OBRA '87"), Pub. L. No. 100-203, 101 Stat. 1330 (1987), Congress substantially revised the statutes regarding the participation of LTC facilities in Medicare and Medicaid. Those changes were prompted by concerns about the treatment and condition of residents. The House Budget Committee, for example, was "deeply troubled by persistent reports that, despite [a] massive commitment of Federal resources, many nursing homes receiving Medicaid funds are providing poor quality care to . . . vulnerable elderly and disabled beneficiaries." H.R. Rep. No. 100-391(I), at 448, 452 (1987). The committee cited a report by the General Accounting Office (now the Government Accountability Office) to the effect that "41 percent of skilled nursing facilities and 34 percent of intermediate care facilities were out of compliance during three consecutive inspections with one or more of the Medicaid requirements most likely to affect

patient health and safety," and that "[n]ursing homes can remain in the Medicare and Medicaid programs for years with serious deficiencies that threaten patient health and safety by taking corrective action to keep from being terminated each time they get caught." *Id*. at 451. The committee also cited a report by the National Academy of Sciences saying that "in many . . . government certified nursing homes, individuals who are admitted receive very inadequate – sometimes shockingly deficient – care that is likely to hasten the deterioration of their physical, mental, and emotional health," and that "the poor-quality [nursing] homes outnumber the very good homes." *Id*. at 452.

Thus, OBRA '87 effectuated a "major overhaul" in the requirements for participation of LTC facilities in Medicare and Medicaid. *Id*. As enacted in OBRA '87 and as now contained in current law, an LTC facility must meet numerous conditions set forth in the governing statute and regulations to participate in these programs. Among other things, the facility must provide nursing services, rehabilitative services, medically-related social services, pharmaceutical services, and other services "to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." 42 U.S.C. §§ 1395i-3(b)(4)(A), 1396r(b)(4)(A). The facility "must protect and promote the rights of each resident," including the right to privacy, the right to confidentiality, the right to right to express grievances, and the right to "prompt efforts by the facility to resolve grievances." *Id*. §§ 1395i-3(c)(1)(A), 1396r(c)(1)(A).

OBRA '87 also expanded the Secretary's responsibilities in relation to the participation of LTC facilities in Medicare and Medicaid. The Secretary is responsible, among other things, for ensuring that the requirements regarding LTC facilities and the enforcement of those requirements are "adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys." *Id*. §§ 1395i-3(f)(1), 1396r(f)(1). In addition to the requirements expressly enumerated in the statutes and regulations, OBRA '87 –

and current law – authorizes the Secretary to impose "such other requirements relating to the health and safety [and well-being] of residents . . . as [she] may find necessary." *Id.* §§ 1395i-3(d)(4)(B), 1396r(d)(4)(B). The Secretary may also establish "other right[s]" for residents, in addition to those expressly set forth in the statutes and regulations, to "protect and promote the rights of each resident." *Id.* §§ 1395i-3(c)(1)(A)(xi), 1396r(c)(1)(A)(xi).

Further, OBRA '87 expanded and strengthened the provisions for monitoring the performance of LTC facilities. Each facility undergoes an annual "standard survey," or inspection, covering "the quality of care furnished, as measured by indicators of medical, nursing, and rehabilitative care, dietary and nutrition services, activities and social participation, and sanitation, infection control, and the physical environment." *Id.* §§ 1395i-3(g)(2)(A)(ii)(I), 1396r(g)(2)(A)(ii)(I). A facility may also be required to undergo a "special survey" within two months of any change of ownership, administration, or management. *Id.* §§ 1395i-3(g)(2)(A)(iii)(II), 1396r(g)(2)(A)(iii)(II). Additionally, any facility found, through a standard survey, to have provided substandard care immediately undergoes an "extended survey" to examine its practices, staffing, and training more thoroughly. *Id.* §§ 1395i-3(g)(2)(B), 1396r(g)(2)(B).

III. Reform of Regulatory Requirements

In July 2015, CMS proposed to revise the regulations governing participation of LTC facilities in Medicare and Medicaid, which had not been comprehensively reviewed and updated since 1991. 80 Fed. Reg. 42,168, 42,169 (July 16, 2015). The changes were meant, among other things, "to improve the quality of life, care, and services in LTC facilities, optimize resident safety, [and] reflect current professional standards." *Id.* The revisions covered a broad range of matters, including resident rights, facility responsibilities, quality of care and quality of life,

quality assurance, protecting residents from abuse and neglect, and specific services provided by the facilities.

In the proposed rule, CMS expressed a number of concerns about the use of agreements requiring residents of LTC facilities to submit any disputes with the facility to binding arbitration. Unlike other forms of alternative dispute resolution, the agency observed, "binding arbitration requires that both parties waive the right to any type of judicial review or relief." *Id.* at 42,211. CMS was concerned about that result in light of "the facilities' superior bargaining power," which "could result in a resident feeling coerced into signing the agreement." *Id.* Also, the agency said, "if the agreement is not explained to the resident, he or she may be waiving an important right, the right to judicial relief, without fully understanding what he or she is waiving." *Id.* Further, the agency expressed concern that "the increasing prevalence of these agreements could be detrimental to residents' health and safety and may create barriers for surveyors and other responsible parties to obtain information related to serious quality of care issues." *Id.* This concern arose out of not only "the residents' waiver of judicial review, but also . . . the possible inclusion of confidentiality clauses that prohibit the resident and others from discussing any incidents with individuals outside the facility, such as surveyors and representatives of the Office of the State Long-Term Care Ombudsman." *Id.*[1]

In light of these concerns, CMS proposed, and requested public comments on, several requirements regarding the execution and content of arbitration agreements, including a requirement that admission to a facility "not be contingent upon the resident or the [resident's] representative signing a binding arbitration agreement." *Id.* at 42,265. Nevertheless, the agency also expressed concern that the requirements it contemplated might be insufficient. CMS was

[1] Each State has a Long-Term Care Ombudsman, who, among other things, resolves complaints from residents and their families, monitors the implementation of applicable statutes and regulations, and represents the interests of residents before governmental agencies. 45 C.F.R. § 1324.13(a).

"concerned that despite the protections we have proposed in this rule, some nursing home residents and potential residents may feel pressured to sign these agreements," such as where a potential resident is hospitalized and has not had "the time to do research and visit multiple homes." *Id*. at 42,242. Therefore, the agency solicited comments on whether arbitration agreements should be prohibited entirely. *Id*. at 42,211, 42,242.

CMS received more than 9,800 public comments on the comprehensive revision of the regulations, almost 1,000 of which related to arbitration. 81 Fed. Reg. 68,688, 68,692, 68,799 (Oct. 4, 2016). The commenters included long-term care consumers, consumer advocacy groups, organizations representing providers, health care associations, legal organizations, and individual health professionals. *Id*. at 68,692. Comments on the arbitration provision expressed a wide range of views. Some commenters argued that even the proposed requirements regarding arbitration agreements were unnecessary, whereas others argued that pre-dispute agreements should be prohibited. *Id*. at 68,790, 68,793. Still others argued that even *post*-dispute arbitration agreements should be prohibited. *Id*. at 68,793.[2]

"[A] number of commenters stated that arbitration clauses have a detrimental effect on patient safety. One commenter, a healthcare provider who had previously treated LTC facility residents, stated that the commenter had personally witnessed resident neglect and attributed it to facilities believing that they were immune to any legal consequences for their mistreatment because of the likelihood that they would prevail in binding arbitration." *Id*. "Other commenters stated that binding arbitration clauses generally cover all claims, including claims involving serious bodily harm and death, and allow facilities to escape accountability for neglect and

[2] A preliminary version of the administrative record regarding the challenged regulation is submitted with Defendants' Response to Plaintiffs' Motion for Preliminary Injunction. As stated in the accompanying Declaration of Sheli E. Harris, this preliminary record was identified on very short notice and is subject to change, and the agency intends to certify a final record at a later date, as appropriate.

abuse." *Id*. Other commenters noted that the "limited discovery generally allowed [in arbitration] puts the resident at a distinct disadvantage." *Id*. at 68,794.

Among other comments, CMS received several items of correspondence from members of Congress and other public officials, including a letter from thirty-four Senators urging the agency to prohibit pre-dispute arbitration agreements, a letter from three members of the House of Representatives arguing against such a prohibition, and a letter from sixteen state attorneys-general stating that pre-dispute arbitration agreements are harmful to residents and should be prohibited. *Id*. at 68,790. One congressional letter pointed out that "individuals seeking long-term care, many of whom are elderly or disabled, are basing their decisions on the cost of care and proximity to their loved ones, and that it would be difficult for these individuals to fully understand the gravity of contract terms and their legal rights . . . concerning potential future disputes between themselves and the facilities." *Id*.

In addition to reviewing the comments received, CMS reviewed relevant literature and court opinions. *Id*. at 68,793. The agency noted that many of the articles it reviewed "provided evidence that predispute arbitration agreements were detrimental to the health and safety of LTC facility residents." *Id*. For example, the articles discussed "the unequal bargaining power between the resident and the LTC facilities; inadequate explanations of the arbitration agreement; the inappropriateness of presenting the agreement upon admission, an extremely stressful time for the residents and their families; negative incentives on staffing and care as a result of not having the threat of a substantial jury verdict for sub-standard care; and the unfairness of the arbitration process for the resident." *Id*. One article, the agency observed, noted that "residents of nursing homes are frail and elderly people who are completely dependent on the facility and its employees for their safety and health." *Id*.

CMS also considered the secrecy of arbitration. The agency found that most arbitration agreements have "confidentiality clauses that prohibit both parties from discussing the dispute and what happens during the arbitration process, including the decision, with outside parties." *Id*. at 68,797. Thus, CMS was "concerned that the arbitration process, especially the secrecy it involves, could result in some facilities evading responsibility for substandard care." *Id*. at 68,797-798. "[P]ublic knowledge about a dispute and a public record of a decision," the agency believed, "are vitally important for checking the worst abuses of non-compliant LTC facilities." *Id*. at 68,794.

After considering all of the factors and discussing them through eight-and-a-half pages in the Federal Register, *see id*. at 68,790-800, CMS became "convinced that requiring residents to sign pre-dispute arbitration agreements is fundamentally unfair because, among other things, it is almost impossible for residents or their decision-makers to give fully informed and voluntary consent to arbitration before a dispute has arisen." *Id*. at 68,792. Thus, the agency decided to promulgate a regulation – now codified at 42 C.F.R. § 483.70(n)(1) – that LTC facilities that participate in Medicare or Medicaid "must not enter into a predispute agreement for binding arbitration with any resident or resident's representative nor require that a resident sign an arbitration agreement as a condition of admission to the LTC facility." 81 Fed. Reg. at 68,867. The agency noted that this approach is a middle ground: "While some commenters have requested that we ban all arbitration, we have determined, at this point, to implement a policy that strikes a balance between banning arbitration in all situations and allowing unfettered use of [post-dispute] arbitration clauses . . . ." *Id*. at 68,799. This approach, CMS observed, would "allow residents to avail themselves of the benefits of arbitration once a dispute has arisen and the resident and/or his/her representatives can determine whether it may be an advantageous forum for them." *Id*. at 68,795.

ARGUMENT

To establish entitlement to a preliminary injunction, the plaintiff must clearly show:

> (1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction is not issued, (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted, and (4) that the grant of an injunction will not disserve the public interest.

Sepulvado v. Jindal, 729 F.3d 413, 417 (5th Cir. 2013). "The Fifth Circuit has deemed the first element to be *sine qua non*, meaning there is no need to proceed to the other elements if a substantial likelihood of success on merits cannot be proven." *Banks v. Davis*, No. 2:13CV16 KS-MTP, 2013 WL 4833892, at *1 (S.D. Miss. Sept. 11, 2013). The second element, irreparable injury, "requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter v. Nat. Res. Def. Council, Inc*., 555 U.S. 7, 22 (2008) (emphasis in original). In short, "[a] preliminary injunction is an extraordinary remedy which should not be granted unless the party seeking it has clearly carried the burden of persuasion on all four requirements." *Bluefield Water Ass'n v. City of Starkville*, 577 F.3d 250, 253 (5th Cir. 2009); *see White v. Carlucci*, 862 F.2d 1209, 1211 (5th Cir. 1989) ("A preliminary injunction is an extraordinary and drastic remedy, not to be granted routinely, but only when the movant, by a clear showing, carries the burden of persuasion.") (internal quotation marks omitted).

As shown below, the plaintiffs cannot satisfy these requirements. On the merits, they argue that 42 C.F.R. § 483.70(n)(1) is beyond the Secretary's authority, that it violates the Federal Arbitration Act, 9 U.S.C. § 2, that the regulation is "arbitrary and capricious" under the Administrative Procedure Act, and that the Secretary failed to comply with the Regulatory Flexibility Act in enacting it. 5 U.S.C. §§ 601-612. All of these arguments must fail, however, which alone requires denying plaintiffs' motion. First, unlike traditional commercial enterprises,

nursing homes participating in Medicare and Medicaid serve "vulnerable elderly and disabled beneficiaries" under a federal program. H.R. Rep. No. 100-391(I), at 452. Thus, Congress requires that they be administered "to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." 42 U.S.C. §§ 1395i-3(b)(4)(A), 1396r(b)(4)(A). And, to that end, Congress has specifically empowered the Secretary to protect the health and welfare of nursing home residents by imposing "other requirements" on nursing homes that participate in Medicare or Medicaid, and by establishing "other rights" for residents of such facilities. *Id.* §§ 1395i-3(c)(1)(A)(xi), (d)(4)(B), 1396r(c)(1)(A)(xi), (d)(4)(B). The challenged regulation is well within that authority.

Second, the Federal Arbitration Act "does not confer a right to compel arbitration of any dispute at any time" and "does not require parties to arbitrate when they have not agreed to do so . . . . It simply requires courts to enforce privately negotiated agreements to arbitrate, like other contracts, in accordance with their terms." *Volt Info. Scis., Inc. v. Bd. of Trustees of Leland Stanford Junior Univ.*, 489 U.S. 468, 474-75, 478 (1989). This Act does not, therefore, apply here. Third, CMS had ample information before it to support the challenged regulation, and its eight-and-half-page discussion in the Federal Register attests that the decision to enact the regulation was anything but "arbitrary" or "capricious." And fourth, the Secretary's discussion of the regulation's impact satisfied the procedural requirements of the Regulatory Flexibility Act, especially when combined with the agency's lengthy Regulatory Impact Analysis under Executive Orders 12,866 and 13,563, 58 Fed. Reg. 51,735 (Sept. 30, 1993); 76 Fed. Reg. 3,821 (Jan. 18, 2011).

In relation to the other requirements for preliminary relief, plaintiffs' claims that the regulation will irreparably harm LTC facilities are based mostly on speculation, which is "not sufficient." *See Morrell v. City of Shreveport*, 536 F. App'x 433, 435 (5th Cir. 2013). In

contrast, granting plaintiffs' motion would inevitably impact residents. The "million or more" Medicare and Medicaid beneficiaries who, plaintiffs believe, will be admitted to nursing homes during the pendency of this action (Doc. 21 at 20) would be presented with binding arbitration agreements at that "extremely stressful" time, 81 Fed. Reg. at 68,796, binding them to that single means of resolving any future dispute, no matter how serious or consequential. That impact clearly outweighs any speculative harm to the facilities from denying plaintiffs' motion, and the public interest – expressed in the statutes and regulations that govern Medicare and Medicaid – counsels allowing 42 C.F.R. § 483.70(n)(1) to go into effect.[3]

I. Plaintiffs Are Unlikely to Succeed on the Merits

A. Section 483.70(n)(1) Is Within the Secretary's Authority

The Social Security Act and its history make clear that Congress is very concerned about protecting nursing home residents, and that it has entrusted the Secretary of Health and Human Services with protecting residents enrolled in Medicare or Medicaid. Congress strengthened and expanded the statutory requirements for the participation of LTC facilities in Medicare and Medicaid specifically because of concerns about "poor quality care" that may "threaten patient health and safety." *See* H.R. Rep. No. 100-391(I), at 448, 451. In light of those concerns, Congress authorized the Secretary to impose "such other requirements relating to the health and safety [and the well-being] of residents . . . as [she] may find necessary," 42 U.S.C. §§ 1395i-3(d)(4)(B), 1396r(d)(4)(B), and to establish "other right[s]" to "protect and promote the rights of

[3] In this action under the Administrative Procedure Act, the Court's analysis should be limited to the administrative record that was before the agency when it promulgated the challenged regulation. *See Kappos v. Hyatt*, 132 S. Ct. 1690, 1696 (2012) ("Under the APA, judicial review of an agency decision is typically limited to the administrative record."); *La Unión del Pueblo Entero v. FEMA*, 141 F. Supp. 3d 681, 693 (S.D. Tex. 2015) ("Under the so-called 'record rule,' a court reviewing agency action under the APA ordinarily cannot review evidence outside of the administrative record.") (internal quotation marks omitted). This Court should not, therefore, consider the declarations submitted with plaintiffs' motion for preliminary injunction.

each resident," in addition to those expressly set forth in the statutes and regulations. *Id.* §§ 1395i-3(c)(1)(A)(xi), 1396r(c)(1)(A)(xi). Both of these authorities support the regulation challenged here. [4]

In promulgating 42 C.F.R. § 483.70(n)(1), CMS found that pre-dispute arbitration agreements "could be detrimental to residents' health and safety," 80 Fed. Reg. at 42,211, and that finding is amply supported by the comments and other information before the agency. That information indicated, for example, that such agreements are normally presented upon admission, which is "an extremely stressful time for the [prospective] resident and his or her family," especially given that the resident "may have a serious injury, surgery, or illness." 81 Fed. Reg. at 68,796. This seriously compromises the ability of the resident or the resident's family to make the best decision for his/her health, safety, and well-being. Additionally, the agency found that arbitration agreements usually contain confidentiality provisions, which "may create barriers for surveyors and other responsible parties to obtain information related to serious quality of care issues," 80 Fed. Reg. at 42,211 – further affecting the health, safety, and well-being of residents. Thus, 42 C.F.R. § 483.70(n)(1) falls within the Secretary's authority to impose "other requirements relating to the health and safety [and the well-being] of residents . . . as [she] may find necessary," 42 U.S.C. §§ 1395i-3(d)(4)(B), 1396r(d)(4)(B).

CMS's findings also fully support its conclusion that a right to avoid pre-dispute arbitration agreements will "protect and promote the rights of each resident." *Id.* §§ 1395i-3(c)(1)(A)(xi), 1396r(c)(1)(A)(xi). Much of the material before the agency attested to the "superior bargaining power" of LTC facilities compared to residents, which "could result in a

[4] To the extent plaintiffs challenge the portion of the regulation relating to participation in the Medicare program, this Court lacks jurisdiction over that challenge because plaintiffs have not received a final decision from the Secretary after pursuing their remedies in Medicare's administrative scheme. *See* 42 U.S.C. §§ 405(h), 1395ii; *Shalala v. Illinois Council on Long-Term Care, Inc.*, 529 U.S. 1, 13 (2000).

resident feeling coerced into signing the agreement. 80 Fed. Reg. at 42,211; *see* 81 Fed. Reg. at 68,793. Some commenters, including a member of Congress, observed that a person being admitted to a nursing home would be unlikely "to fully understand the gravity of contract terms and their legal rights . . . concerning potential future disputes between themselves and the facilities." *Id*. at 68,790. In light of these circumstances and others considered by the agency, establishing a right for residents to avoid pre-dispute arbitration agreements falls well within the Secretary's authority to establish "other right[s]" to "protect and promote the rights of each resident." 42 U.S.C. §§ 1395i-3(c)(1)(A)(xi), 1396r(c)(1)(A)(xi).[5]

Moreover, as discussed above, Congress authorized the Secretary to impose "other requirements" and to establish "other rights," *see id*. §§ 1395i-3(c)(1)(A)(xi), (d)(4)(B), 1396r(c)(1)(A)(xi), (d)(4)(B), because of its concern that "vulnerable elderly and disabled beneficiaries" were receiving "poor quality care" in nursing homes. *See* H.R. Rep. No. 100-391(I), at 448, 452. The Secretary promulgated 42 C.F.R. § 483.70(n)(1) precisely to protect "vulnerable" Medicare and Medicaid beneficiaries and to ensure that they receive "quality care." If the Secretary's statutory authority to impose "other requirements" and to establish "other rights" means anything, it encompasses the regulation challenged here.[6]

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[5] In light of the unique circumstances of nursing home residents and Congress's concern for protecting them, this case is readily distinguishable from *Associated Builders and Contractors of Southeast Texas v. Rung*, No. 16-cv-00425 (E.D. Tex.), discussed by *amicus* U.S. Chamber of Commerce (Doc. 30 at 19), which involved arbitration between government contractors and their employees.

[6] The challenged regulation also falls within the Secretary's general statutory authorities to enact "regulations, not inconsistent with [the Social Security Act], as may be necessary to the efficient administration of the functions with which [she] is charged under [the Act]," 42 U.S.C. § 1302(a), and, more specifically, to "prescribe such regulations as may be necessary to carry out the administration of the [Medicare program]," *id*. § 1395hh(a). Plaintiffs assert that these authorities only relate to the internal functioning of the Department of Health and Human Services itself (Doc. 21 at 11). But the plain language of the statutes belies that assertion: they apply to the administration of the Secretary's functions *under the Social Security Act* and to the administration *of Medicare*.

Even if there were any uncertainty as to whether these statutory authorities include the power to prohibit pre-dispute arbitration agreements, the Court should defer to the Secretary's conclusion that they do. As noted above, the Secretary of Health and Human Services and the Administrator of CMS are entrusted with administering the Social Security Act and its Medicare and Medicaid provisions. And Congress particularly granted the Secretary broad authority to impose additional requirements on nursing homes that participate in Medicare or Medicaid to protect the rights of residents. The Supreme Court has "long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer." *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 844 (1984). Therefore, even without the history and congressional concern reflected in OBRA '87, the Court should defer to the Secretary's understanding of these statutory authorities.

Plaintiffs argue that these authorities cannot encompass the challenged regulation because "[w]hether disputes are resolved in judicial proceedings or arbitration" is not related to the "health and safety [and well-being] of residents," which is the focus of the statutes (Doc. 21 at 11, 14). *See* 42 U.S.C. §§ 1395i-3(c)(1)(A)(xi), (d)(4)(B), 1396r(c)(1)(A)(xi), (d)(4)(B). Plaintiffs' own arguments contradict this assertion, however. They argue that the use of arbitration allows facilities to spend more money on caring for residents and that prohibiting pre-dispute arbitration agreements would "threaten the care and well-being of residents and patients" (Doc. 21 at 2, 20-21, 23). Thus, in reality, the plaintiffs and the defendants *agree* that whether or not residents are required to sign pre-dispute agreements affects the health, safety, and well-being of residents – such that the Secretary's decision on that issue is well within her statutory authority. That the plaintiffs disagree with the Secretary's choice in exercising that authority does not mean that the Secretary acted outside her authority.

Plaintiffs' other arguments go to the wisdom of prohibiting pre-dispute arbitration agreements rather than to the Secretary's authority (Doc. 21 at 12-13). As summarized above, however, CMS had ample information before it to support the reasonableness of its decision, and most of that information *did not* come from "plaintiffs' lawyers" (Doc. 21 at 13). Nor does the existence of the Federal Arbitration Act suggest that the Secretary should have reached a different conclusion (Doc. 21 at 12). The FAA expresses a general policy to enforce arbitration agreements, not to require contracting parties in all circumstances to enter into such agreements in the first place. Finally, the potential for a court to "invalidate arbitration agreements" does not render unreasonable the Secretary's exercise of her authority (Doc. 21 at 12). The information before the agency indicated that prospective nursing home residents are unlikely, before a potentially arbitrable dispute arises, to be fully aware of their rights or to understand fully "the gravity of the contract terms." *See* 81 Fed. Reg. at 68,790. The agency need not, therefore, have relied on the possibility that a resident unfairly forced to execute an improper arbitration agreement would be sufficiently aware of his rights to challenge the agreement in court.

B. Section 483.70(n)(1) Is Not in Conflict with the Federal Arbitration Act

Congress enacted the Federal Arbitration Act ("FAA" or "Act") in 1925, "in response to widespread judicial hostility to arbitration agreements." *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 339 (2011). The "primary substantive provision of the Act" is Section 2, *Moses H. Cone Mem'l Hosp. v. Mercury Constr. Corp.*, 460 U.S. 1, 24 (1983), which provides that arbitration agreements are enforceable:

> A written provision in . . . a contract evidencing a transaction involving commerce to settle by arbitration a controversy thereafter arising out of such contract or transaction, or the refusal to perform the whole or any part thereof, or an agreement in writing to submit to arbitration an existing controversy arising out of such a contract, transaction, or refusal, shall be valid, irrevocable, and enforceable, save upon such grounds as exist at law or in equity for the revocation of any contract.

9 U.S.C. § 2. Other provisions in the Act support that purpose. Most notably, "[a] party aggrieved by the alleged failure, neglect, or refusal of another [party] to arbitrate under a written agreement for arbitration may petition any United States district court" that would have jurisdiction over the underlying substantive controversy "for an order directing that such arbitration proceed in the manner provided for in such agreement." *Id*. § 4; *see Vaden v. Discover Bank*, 556 U.S. 49, 58-65 (2009) (discussing jurisdiction over underlying controversy). "The Act also supplies mechanisms for enforcing arbitration awards." *Hall St. Assocs., L.L.C. v. Mattel, Inc.*, 552 U.S. 576, 582 (2008).

The Supreme Court has emphasized that "the FAA does not require parties to arbitrate when they have not agreed to do so . . . . It simply requires courts to enforce privately negotiated agreements to arbitrate, like other contracts, in accordance with their terms." *Volt Info. Scis., Inc. v. Bd. of Trustees of Leland Stanford Junior Univ.*, 489 U.S. 468, 478 (1989). Thus, "the FAA does not confer a right to compel arbitration of any dispute at any time; it confers only the right to obtain an order directing that 'arbitration proceed *in the manner provided for in [the parties'] agreement.*" 9 U.S.C. § 4 (emphasis added)." *Id*. at 474-75. In other words, the Court said, "[t]here is no federal policy favoring arbitration under a certain set of procedural rules; the federal policy is simply to ensure the enforceability, according to their terms, of private agreements to arbitrate." *Id*. at 476. In short, "[a]rbitration under the Act is a matter of consent, not coercion." *Id.* at 479; *see Fleetwood Enterprises, Inc. v. Gaskamp*, 280 F.3d 1069, 1073 (5th Cir. 2002) ("In adjudicating a motion to compel arbitration under the Federal Arbitration Act, courts begin by determining whether the parties agreed to arbitrate the dispute.").

Similarly, the Supreme Court has rejected an argument that an arbitration agreement should not be enforced where such enforcement could lead to the "inefficient maintenance of

separate proceedings in different forums." See *Dean Witter Reynolds, Inc. v. Byrd*, 470 U.S. 213, 217 (1985). The Court said:

> The legislative history of the Act establishes that the purpose behind its passage was to ensure judicial enforcement of privately made agreements to arbitrate. We therefore reject the suggestion that the overriding goal of the Arbitration Act was to promote the expeditious resolution of claims. *The Act, after all, does not mandate the arbitration of all claims, but merely the enforcement – upon the motion of one of the parties – of privately negotiated arbitration agreements.*

Id. at 219 (emphasis added).[7]

As reflected in *Dean Witter Reynolds, Inc.*, a court's responsibility is to apply a federal statute "according to its terms." *United States v. Ron Pair Enters., Inc.*, 489 U.S. 235, 241 (1989) ("[W]here, as here, the statute's language is plain, the sole function of the courts is to enforce it according to its terms.") (internal quotation marks omitted). Only if the statute is ambiguous may the court consult the policy behind the statute, *see Sunshine Haven Nursing Operations, LLC v. HHS., Centers for Medicare & Medicaid Servs.*, 742 F.3d 1239, 1250 (10th Cir. 2014), and "extrinsic policy considerations" cannot be used to "inject ambiguity into the text of an unambiguous statute," *Aragón-Salazar v. Holder*, 769 F.3d 699, 706 (9th Cir. 2014).

According to the plain language of the FAA (and Supreme Court precedent), the statute simply requires the courts to enforce arbitration agreements entered into by parties. Thus, it does not prevent the Secretary of Health and Human Services, in the exercise of her clear statutory authority, from prohibiting the execution of new pre-dispute arbitration agreements for residents in Medicare- or Medicaid-participating LTC facilities. As the agency emphasized in enacting 42

[7] Also reflecting this determination to apply the FAA according to its terms but no further, the Supreme Court has rejected a contention that "the proarbitration policy goals of the FAA" prevented the Equal Employment Opportunity Commission from seeking relief for a former employee under the Americans with Disabilities Act where the employee – but not the EEOC – had agreed to arbitrate any dispute arising out of his employment. *EEOC v. Waffle House, Inc.*, 534 U.S. 279, 294 (2002).

C.F.R. § 483.70(n)(1), the regulation "does not have any effect on existing arbitration agreements or render them unenforceable." 81 Fed. Reg. at 68,800.

Moreover, the Secretary has not purported to regulate nursing homes' use of arbitration agreements as a general matter, but instead has exercised her authority to establish the conditions for participation in the Medicare and Medicaid programs. *See id*. at 68,792, 68,800. A nursing home's participation in these programs is entirely voluntary, and the Secretary is fully empowered to impose reasonable conditions on that participation. *See, e.g.*, *Burditt v. Dep't of Health & Human Servs*., 934 F.2d 1362, 1376 (5th Cir. 1991).[8] Conversely, a nursing home that does not participate in Medicare or Medicaid is not subject to the regulation. There is, therefore, no conflict between the FAA and the Medicare and Medicaid statutes that would require any analysis regarding whether the latter statutes "override" the former, under cases such as *CompuCredit Corp. v. Greenwood,* 132 S. Ct. 665 (2012).[9]

Plaintiffs argue that the Secretary cannot prohibit pre-dispute arbitration agreements by regulation because bills to enact the same prohibition legislatively have failed to pass (Doc. 21 at 8). The courts have consistently declined, however, to infer congressional intent from a failure

[8] Plaintiffs also purport (Doc. 21 at 10) to challenge the voluntariness of the regulation under *National Federation of Independent Business v. Sebelius*, 132 S. Ct. 2566, 2605 (2012) (plurality). This case does not even remotely implicate the concerns of coercion at issue in that decision. *See Mississippi Comm'n on Envtl. Quality v. EPA*, 790 F.3d 138, 175-79 (D.C. Cir. 2015); *Mayhew v. Burwell*, 772 F.3d 80, 88-92 (1st Cir. 2014).

[9] In any event, the Secretary exercised her expressly-granted power to issue legislative regulations to create additional requirements and additional rights to protect the health and safety of residents of Medicare- or Medicaid-participating nursing homes. If any such analysis were needed, the relevant comparison under *Chevron* would be between the FAA and the Secretary's regulations. *Cf. In re Cajun Elec. Power Co-op.*, 109 F.3d 248, 254 (5th Cir. 1997) (noting that whether a federal regulation pre-empts a state law does not turn on an express statement by Congress, but on whether the agency expressed a pre-emptive intent). Here, of course, the Secretary's legislative rule makes perfectly clear her intent to impose conditions on the use of arbitration agreements by nursing homes that participate in her programs. (*Walton v. Rose Mobile Homes LLC*, 298 F.3d 470 (5th Cir. 2002), is not to the contrary. That case held, in a different context, that the agency had misinterpreted Congress's intent to override the FAA. This case, instead, involves a broad grant of legislative rulemaking authority, and there is no genuine issue as to the breadth of that statutory grant.)

or refusal to pass legislation. As Justice Scalia has written: "Congress cannot express its will by a *failure* to legislate. The act of refusing to enact a law (if that can be called an act) has utterly no legal effect, and thus has utterly no place in a serious discussion of the law." *United States v. Estate of Romani*, 523 U.S. 517, 535 (1998) (Scalia, J., concurring) (emphasis in original); *see Atkinson v. Inter-Am. Dev. Bank*, 156 F.3d 1335, 1342 (D.C. Cir. 1998) ("Congress does not express its intent by a failure to legislate."). The Supreme Court has observed that "[c]ongressional inaction lacks persuasive significance because several equally tenable inferences may be drawn from such inaction . . . ." *Pension Ben. Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 650 (1990) (internal quotation marks omitted). For example, "[c]ongressional inaction frequently betokens unawareness, preoccupation, or paralysis." *Zuber v. Allen*, 396 U.S. 168, 185 n.21 (1969). In relation to this case, assuming the failure of legislative proposals to prohibit pre-dispute arbitration agreements means anything, it could evince, not a congressional intent to permit them, but a belief that the Secretary of Health and Human Services has the authority to enact such a prohibition by regulation if she finds it advisable. *Cf. In re Motors Liquidation Co.*, 430 B.R. 65, 95 (S.D.N.Y. 2010) ("It is just as likely that Congress declined to pass the legislation on account of a view that Treasury's authority under [the statute] was adequate to protect the automotive industry.").

C. Section 483.70(n)(1) Is Reasonable and Not Arbitrary or Capricious

Judicial review of agency action under the arbitrary-and-capricious standard is "narrow," and a court "must be mindful not to substitute [its] judgment for the agency's." *10 Ring Precision, Inc. v. Jones*, 722 F.3d 711, 723 (5th Cir. 2013) (citing *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983)). The court should "ensure that the agency examined the relevant data," based its decision on "a consideration of relevant factors," and "articulated a satisfactory explanation for its action." *Id*. (internal quotation marks

omitted). The court "will uphold an agency's action if its reasons and policy choices satisfy minimum standards of rationality." *Id*. Defendants' decision to promulgate 42 C.F.R. § 483.70(n)(1) easily satisfies this standard.

As noted already, CMS had ample information before it to support its decision to prohibit pre-dispute arbitration agreements. Some of the comments and other information before the agency indicated that all arbitration agreements – pre-dispute and post-dispute – should be prohibited, and other comments indicated that the Secretary should take no action. As the agency observed, "a number of commenters stated that arbitration clauses have a detrimental effect on patient safety," and the agency's information included "input from healthcare providers with experience working in or surveying LTC facilities." 81 Fed. Reg. at 68,793, 68,795. Many members of Congress, including more than one-third of the Senate, urged prohibiting pre-dispute arbitration agreements, and three members of the House of Representatives urged the agency not to act at all. *Id*. at 68,790. The agency's final rule discussed at length the information before it. Based on all of the comments and other information on the issue, the Secretary chose a middle course, prohibiting only pre-dispute agreements. That outcome, the extensive record before the agency, and the thorough discussion in the final rule belie any whiff of "arbitrariness" or "capriciousness."[10]

Plaintiffs argue that 42 C.F.R. § 483.70(n)(1) is necessarily arbitrary and capricious because the agency previously supported the existence of pre-dispute arbitration agreements (Doc. 21 at 14-15). As the Supreme Court has noted, however, "the mere fact that an agency interpretation contradicts a prior agency position is not fatal." *Smiley v. Citibank (S. Dakota), N.A.*, 517 U.S. 735, 742 (1996). An agency is "free within the limits of reasoned interpretation

[10] The *amicus* brief of the U.S. Chamber of Commerce describes various alleged benefits of arbitration (Doc. 30). But defendants considered those arguments and others during the regulatory process, and made the reasonable choice to prohibit pre-dispute arbitration agreements.

to change course if it adequately justifies the change." *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 1001 (2005); *see FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (holding that there is no heightened standard for review of agency changes in position, as long as agency is aware it is doing so). Indeed, here, CMS has not changed a statutory or regulatory "interpretation," but only its policy regarding pre-dispute arbitration agreements. That change, moreover, is more than "adequately" explained in the agency's final rule, *see* 81 Fed. Reg. at 68,790-800, which represents the first time CMS or the Department of Health and Human Services has systematically studied the issue and considered a range of public comments. And, of course, the Secretary displayed her awareness that she was imposing a new condition on participating nursing homes in promulgating this regulation. Nothing more is required under the Administrative Procedure Act.

Plaintiffs also argue that the challenged regulation is arbitrary and capricious because it "will have the practical effect of eliminating *all* arbitration agreements in the long-term care profession" because "the parties rarely agree to arbitration" once a dispute has arisen and "they have acquired an emotional investment in the case" (Doc. 21 at 16, 18). Plaintiffs also assert that residents are more "able to pursue their best interests rationally" before a dispute arises (Doc. 21 at 18). To the contrary, however, the information before the agency indicated that admission into a Long-Term Care facility – when facilities usually present the arbitration agreement for signing – is "an extremely stressful time for [prospective] residents and their families," and that "it is almost impossible for residents or their decision-makers to give fully informed and voluntary consent to arbitration before a dispute has arisen" and the parameters of the dispute are known. 81 Fed. Reg. at 68,792, 68,793. Based on all the information before it, the agency reasonably concluded that a prohibition against pre-dispute arbitration agreements would "allow residents to avail themselves of the benefits of arbitration once a dispute has arisen and the resident and/or

his/her representatives can determine whether it may be an advantageous forum for them." *Id*. at 68,795. If, as plaintiffs contend, nursing home residents rarely choose arbitration once a dispute has arisen, perhaps the residents believe that litigation, rather than arbitration, would be better for them. Indeed, according to the plaintiffs, existing residents are unwilling to enter into arbitration agreements even *after* admission but *before* any dispute arises (Doc 21 at 22), further suggesting that residents are willing to sign such agreements only when they feel coerced to do so as part of the admission process.

Lastly, plaintiffs argue that 42 C.F.R. § 483.70(n)(1) is "unnecessary" because the courts can invalidate unconscionable arbitration agreements (Doc. 21 at 5, 17). First, the question here is not whether the challenged regulation is "necessary," but whether it is arbitrary and capricious – that is, whether the agency "examined the relevant data," based its decision on "a consideration of relevant factors," and "articulated a satisfactory explanation for its action." *See 10 Ring Precision, Inc.*, 722 F.3d at 723. As discussed above and as reflected in eight and one-half small-print pages of the Federal Register, the agency did so. *See* 81 Fed. Reg. at 68,790-800.

In any event, CMS rationally decided not to rely on the potential for a resident to challenge an arbitration agreement in court. As the agency observed, "Medicare and Medicaid beneficiaries are aged or disabled and ill," and many "lack the resources to litigate a malpractice claim, much less an initial claim seeking to invalidate an arbitration clause." *Id*. at 68,792. Thus, the agency determined that an outright prohibition would be better "than requiring Medicare and Medicaid beneficiaries to incur the additional fees, expense, and delay that would be the direct cost of opposing a motion to enforce arbitration." *Id*. That choice more than satisfies "minimum standards of rationality." *See 10 Ring Precision, Inc.*, 722 F.3d at 723.

D. The Secretary Complied with the Regulatory Flexibility Act

Several provisions of law require agencies to consider the impacts of their regulatory changes. The Regulatory Flexibility Act ("RFA") generally requires an agency that "promulgates a final rule" to "prepare a final regulatory flexibility analysis." 5 U.S.C. § 604(a). That requirement does not apply, however, where the agency certifies that the regulation "will not . . . have a significant economic impact on a substantial number of small entities." *Id*. § 605(b). Similarly, Executive Orders 12,866 and 13,563 require an agency to prepare an analysis of every "significant regulatory action," including analyzing its costs and benefits. 58 Fed. Reg. 51,735, § 6(a)(3)(C) (Sept. 30, 1993); *see* 76 Fed. Reg. 3,821 (Jan. 18, 2011).

Plaintiffs contend that the defendants failed to comply with the RFA in relation to 42 C.F.R. § 483.70(n)(1). The RFA, however, "is a procedural rather than substantive agency mandate," prescribing no specific outcome and imposing no requirement that an agency adopt substantive measures to reduce the impact of regulations on small business. *See Ass'n of Am. Physicians & Surgeons, Inc. v. HHS*, 224 F. Supp. 2d 1115, 1128 (S.D. Tex. 2002). A court reviews agency compliance with the RFA "only to determine whether an agency has made a reasonable, good-faith effort to carry out [the statute's] mandate." *Alenco Commc'ns, Inc. v. FCC*, 201 F.3d 608, 625 (5th Cir. 2000) (internal quotation marks omitted). The court's review of an agency's certification under 5 U.S.C. § 604(b) is "highly deferential, 'particularly . . . with regard to an agency's predictive judgments about the likely economic effects of a rule.'" *Helicopter Ass'n Int'l, Inc. v. FAA*, 722 F.3d 430, 432-33 (D.C. Cir. 2013) (quoting *Nat'l Tel. Coop. Ass'n v. FCC*, 563 F.3d 536, 541 (D.C. Cir. 2009)).

Here, in both the proposed rule and the final rule, the Secretary engaged in a detailed Regulatory Impact Analysis under Executive Orders 12,866 and 13,563 – covering six pages of the proposed rule and ten and one-half pages of the final rule. *See* 80 Fed. Reg. at 42,235-240;

81 Fed. Reg. at 68,836-946. That analysis included a lengthy, detailed discussion of the costs associated with the final rule. *Id*. at 68,838-844. Turning to the Regulatory Flexibility Act in the final rule, the Secretary referred to the Regulatory Impact Analysis and certified that the final rule would "not have a significant economic impact on a substantial number of small entities." *Id*. at 68,846. With this certification, the Secretary fully discharged her obligations under the RFA, and this Court's inquiry is at an end. *See* 5 U.S.C. § 605(b).

Although plaintiffs may disagree with the Secretary's analysis or wish it had been more detailed, that does not make out a violation of the RFA. In reviewing a challenge under the RFA, "[t]he proper question . . . is not whether the [agency] reached the 'correct' determination, but whether the agency followed the procedural steps set out in the RFA." *Grocery Servs., Inc. v. USDA Food & Nutrition Serv*., No. CIV.A. H-06-2354, 2007 WL 2872876, at *10 (S.D. Tex. Sept. 27, 2007); *see N.C. Fisheries Ass'n v. Gutierrez*, 518 F. Supp. 2d 62, 95 (D.D.C. 2007) ("[A] court reviewing a RFA-based challenge does not evaluate whether the agency got the required analysis right, but instead examines whether the agency has followed the procedural steps laid out in the statute."). Plaintiffs fault the Secretary for not engaging in a more detailed, provision-by-provision analysis of the entire rule (which addressed a number of subjects in addition to arbitration), but nothing in the FRA requires such specificity, and courts are not authorized to impose additional rulemaking procedures beyond those that Congress has established. *See Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1207 (2015). In this case, the Secretary followed the steps prescribed by the statute. Moreover, even if this Court were to find that the Secretary had failed to comply with the RFA, given the strong public interest in favor of her regulation, the correct remedy would be to remand the regulation to the agency for further analysis, not to invalidate it. 5 U.S.C. § 611(a)(4)(A).

II. Plaintiffs Have Failed to Make an Adequate Showing of Irreparable Harm

In *Winter v. Natural Resources Defense Council*, the Supreme Court "raised the bar on what must be shown on the irreparable harm prong to justify a preliminary injunction." *Leiva-Pérez v. Holder*, 640 F.3d 962, 966 (9th Cir. 2011). There the Court said, "Our frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely* in the absence of an injunction." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008) (emphasis in original). The Court of Appeals echoes that "[t]here must be a *likelihood* that irreparable harm will occur. Speculative injury is not sufficient . . . ." *Morrell v. City of Shreveport*, 536 F. App'x 433, 435 (5th Cir. 2013) (emphasis in original).

Here, a number of the harms on which plaintiffs rely are speculative. First, plaintiffs surmise that an absence of pre-dispute arbitration agreements will result in "a spike in the filing of meritless lawsuits, as some members of the plaintiffs' bar may try to leverage the sudden increase in SNFs'/NFs' defense costs to obtain windfall settlements for baseless claims that would never have been filed in arbitration" (Doc. 21 at 21). Many elements of this assertion are rank speculation, including a "spike" in litigation once the regulation becomes effective, the "baselessness" of the new actions, and the motive for filing them. *Cf. Am. Cent. E. Texas Gas Co. v. Union Pac. Res. Grp., Inc.*, No. 2:98CV0239-TJW, 2000 WL 33176064, at *2 (E.D. Tex. July 27, 2000) (rejecting "threat of ancillary litigation from other [private parties]" as irreparable injury); *Atl. Richfield Co. v. Dep't of Energy*, No. CIVIL 82-3269, 1983 WL 1111, at *7 (D.D.C. Jan. 7, 1983) ("[P]laintiff's claim that [the agency's] actions may generate private litigation is purely speculative and thus, is not a basis for establishing irreparable injury in this case."). Indeed, even closer to the facts of this case, one court declined to enjoin the filing of a lawsuit by an employee who had executed an arbitration agreement, with the observation that "[t]he threat of facing multiple, substantially similar, lawsuits does not constitute a threat of irreparable

injury." *Covarrubias v. Ralph's Grocery Co.*, No. C 02-5465 JSW, 2004 WL 2002451, at *2 (N.D. Cal. Sept. 7, 2004).

Second, plaintiffs assert that the challenged regulation will "inevitably lead to an increase in insurance premiums" for LTC facilities (Doc. 21 at 21). The evidence presented on that issue does not support plaintiffs' assertion, however. They submit a letter from a single insurance agency that "reached out" to other agencies informally and posed admittedly "cursory questions" about whether the challenged regulation would result in higher premiums (Doc. 21-3, Ex. 2). The insurance agency reportedly spoke with individual "underwriters" at several other agencies, who said they "felt" the regulation would have a "negative impact" on premiums (*id.*). In fact, the writer of the letter was apparently unaware of the actual nature of the challenged regulation, characterizing it as "disallow[ing] nursing homes from utilizing arbitration agreements" (*id.*). Besides that letter, plaintiffs cite the unsubstantiated statement of one of the plaintiffs' officers that "the potential for increased [insurance] premiums is likely" (Doc. 20-1 ¶ 9). This is not the kind of evidence needed to establish irreparable harm.[11]

Third, plaintiffs assert that, if one of the plaintiffs or another LTC facility chose to continue entering into pre-dispute arbitration agreements despite the regulatory prohibition, CMS could fine the facility "up to $20,628 per incident for each day," which "would bankrupt" any facility (Doc. 21 at 20). This assumes, however, that a facility approved to provide services to Medicare and Medicaid beneficiaries would choose to defy a federal regulation, which is highly speculative at best. Moreover, this assertion is based on CMS's discretionary authority to impose a penalty for failure to comply with certain requirements of the statute and regulations,

[11] In any event, to the extent eliminating pre-dispute arbitration agreements results in increased insurance premiums, that may reflect a recognition that litigation will reveal conduct that would not otherwise come to light and result in jury awards that would not otherwise have been entered – thus supporting the concern that pre-dispute arbitration agreements may "allow facilities to escape accountability for neglect and abuse." 81 Fed. Reg. at 68,793.

see 42 U.S.C. §§ 1395i-3(h)(2), 1396r(h)(2), and is thus based on several assumptions, including that the agency would exercise its authority to impose a penalty, that it would impose the maximum penalty, *see* 42 C.F.R. § 488.404 (factors to be considered in selecting remedies), and that any administrative challenge by the facility would be unsuccessful. *See id.* § 488.331 (informal dispute resolution), § 488.438(e) (review of monetary penalty), § 498.5(c) (appeal to Departmental Appeals Board).

Moreover, this is a case proceeding on an administrative record, and the full action on the merits could be briefed promptly once the certified record is submitted to the Court (as it soon will be). A reasonable briefing schedule would call for submission of the case within a few months, and the Court could rule on the merits shortly thereafter. Plaintiffs have made no showing that they face irreparable harm at all, and they certainly have not shown that they face irreparable harm in the short interval that would be needed for this case to proceed to final judgment.

In sum, plaintiffs' speculations do not establish that "irreparable injury is *likely* in the absence of an injunction." *See Winter*, 555 U.S. at 22.

III. The Harm to Nursing Home Residents from Granting Relief Would Outweigh any Harm to the Plaintiffs from Denying It

Plaintiffs' speculations of harm contrast sharply with the Secretary's findings regarding the impact of pre-dispute arbitration agreements on residents, which are based on almost 1,000 comments from the public, a review of relevant literature, and communications from members of Congress. 81 Fed. Reg. at 68,790, 68,793, 68,799. Nursing home residents, many of whom are frail, elderly, and/or disabled, must enter into these agreements at an "extremely stressful" time and without adequate information. *Id.* at 68,790, 68,793, 68,796. The agreements purport to

bind them to one means of resolving any future dispute with the facility, before they can know the nature or seriousness of the dispute. *Id*. at 68,790, 68,792, 68,793.

Plaintiffs themselves assert that "[a] million or more new residents and patients" will probably be admitted to LTC facilities under Medicare or Medicaid during the pendency of this action (Doc. 21 at 20). If the requested preliminary injunction were granted, all or nearly all of those residents would probably enter into pre-dispute arbitration agreements as a condition of admission. They would then be bound to that one means of resolving any dispute with their nursing home, not only for the duration of this litigation, but also for the duration of their stay and "some for the rest of their lives." 81 Fed. Reg. at 68,792. This consequence for "a million or more" individuals and their families clearly outweighs any contrary speculative harm to the plaintiffs.

IV. A Preliminary Injunction Would Disserve the Public Interest

As discussed above, Congress has expressed great concern for the welfare of nursing home residents under Medicare and Medicaid, and has entrusted the Secretary of Health and Human Services with protecting them. *See* H.R. Rep. No. 100-391(I), at 448, 452; 42 §§ 1395i-3(c)(1)(A)(xi), (d)(4)(B), 1396r(c)(1)(A)(xi), (d)(4)(B). Protecting the interests of those residents is, therefore, part of the "public interest," which thus militates against the requested preliminary injunction for the same reasons stated in Part III immediately above.

The public interest disfavors plaintiffs' motion for the additional reason that most arbitration agreements have "confidentiality clauses that prohibit both parties from discussing the dispute and what happens during the arbitration process, including the decision, with outside parties." 81 Fed. Reg. at 68,797. Such clauses limit the information available to both government representatives and the public in general. They "prohibit the resident and others from discussing any incidents with individuals outside the facility, such as surveyors and representa-

tives of the Office of the State Long-Term Care Ombudsman." 80 Fed. Reg. at 42,211. And, as the Secretary has said, "public knowledge about a dispute and a public record of a decision are vitally important for checking the worst abuses of non-compliant LTC facilities." 81 Fed. Reg. at 68,794. In this case, therefore, the public interest arises partly out of what (legitimately) interests the public.

CONCLUSION

Accordingly, plaintiffs' motion for preliminary injunction should be denied.

Dated: October 28, 2016

Respectfully submitted,

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